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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,426	04/24/2001	Jonathan W. Nyce	EPI-00311	5444
26380	7590	10/01/2003	EXAMINER	
EPIGENESIS PHARMACEUTICALS 7 CLARK DRIVE CANBURY, NJ 08520			JIANG, SHAOJIA A	
		ART UNIT	PAPER NUMBER	
		1617	DATE MAILED: 10/01/2003	

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/841,426	NYCE, JONATHAN W.
<b>Examiner</b>	<b>Art Unit</b>	
Shaojia A Jiang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 09 July 2003.

2a) This action is FINAL.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-79 is/are pending in the application.

4a) Of the above claim(s) 16 and 49-79 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-15 and 17-48 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ .
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) <input type="checkbox"/> Other: _____ .	

### **DETAILED ACTION**

This Office Action is a response to Applicant's amendment and response filed on July 9, 2003 in Paper No. 10 wherein 1-15 and 17-48 have been amended. It is noted that Applicant states in the response that "Claims 16 and 49-79 are withdraw". Thus, it is unclear whether Applicant intended to cancel claims 16 and 49-79.

Currently, claims 1-79 are pending in this application.

A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment filed on July 9, 2003 in Paper No. 10 with respect to the rejection of claims 5-6, 17, 19-28 and 32-48 made under 35 U.S.C. 112 second paragraph for indefinite expressions, i.e., "active agent ", " other therapeutic agents", "the formulation", and "the kit" of record stated in the Office Action dated December 18, 2002 have been fully considered and found persuasive to remove the rejection since these indefinite expressions have been removed.

The following are new rejections necessitated by Applicant's amendment filed on July 9, 2003 in Paper No. 10, wherein the limitations in all pending claims as amended now have been changed since the recitation "optionally" in claim 1 has been deleted.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 and 17-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Nyce (5,527,789, of record).

Nyce discloses a pharmaceutical composition comprising the instant DHEA having the chemical formula (I) in a therapeutically effective amounts and the instant ubiquinone having the chemical formula (II) with n being from 1 to 12, 1 to 10, 6 to 10, or 10, in the therapeutically effective amounts, and a pharmaceutical carrier or diluent (see abstract, claims 13-19). Nyce also discloses the particular effective amounts of DHEA, i.e., 1-3600 mg/kg, 5-1800 mg/kg, or 20-100 mg/kg (see col.6 lines 6-7); and the particular effective amounts of ubiquinone, i.e., 1-1200 mg/kg, 30-600 mg/kg, or 50-150 mg/kg (see col.5 lines 64-66), within the instant claimed range, about 0.1-49% or about 1-20% w/w, since converting the known actual amount by actual weight to weight percentage in a compositon, w/w, is considered well within conventional skills in pharmaceutical science, involving merely routine skill in the art. The pharmaceutical composition of Nyce further comprises a preservative, an antioxidant, a flavoring agent (e.g., sugar, see col.7 line 10), a buffering agent, a dispersant, or a surfactant (see col.6 line 67 to col.8 line 1, and col.7 lines 33-38) an inert base, glycerol (glycerin, see col.7 line 11-12). Nyce also discloses the instant forms of the formulation, e.g., oral, rectal, topical, transdermal, nasal, or parenteral including injectable (see col.5 lines 37-41,

col.6 lines 40-67), in a solution (an aqueous liquor), suspension or emulsion (see col.6 lines 45-61).

Thus, Nyce anticipates claims 1-15 and 17-41.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-48 are rejected under 35 U.S.C. 103(a) as being unpatentable Nyce (5,527,789, of record).

The same disclosures of Nyce has been discussed above (see supra at page 3-4).

The cited prior art does not expressly disclose employ a kit comprising the same composition.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to put the same composition in to a kit.

One having ordinary skill in the art at the time the invention was made would have been motivated to put the same composition in to a kit because the employment of a known kit comprising a known pharmaceutical composition is considered well within conventional skills in pharmaceutical science, involving merely routine skill in the art.

Thus the claimed invention as a whole is clearly *prima facie* obvious over the combined teachings of the prior art.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-15 and 17-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-19 of U.S. Patent No. 5,527,789 (of record).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent are drawn to a pharmaceutical composition comprising the dehydroepiandrosterone and ubiquinone with n being from 1 to 10, 6 to 10, or 10, and pharmaceutically acceptable carrier such as an aqueous or a solid carrier. The claim of the instant application is drawn to a pharmaceutical composition or formulation, or kit comprising the same dehydroepiandrosterone and ubiquinone with n being from 1 to 12, 1 to 10, 6 to 10, or 10, in the effective amounts, and

pharmaceutically acceptable carrier such as an aqueous or a solid carrier, and this pharmaceutical composition or formulation, or kit may be further comprises other agents such as preservatives, antioxidants flavoring agents, volatile oils, buffering agents, dispersants or surfactants, as discussed above (see supra at page 3-4).

Therefore, the claimed invention in claims 1-15 and 17-48 is clearly seen to be anticipated by claims 13-19 of U.S. Patent No. 5,527,789.

Claims 1-15 and 17-48 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 159 of copending Application No. 10/072,010.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both the claim copending application and the claim of the instant application are drawn to the same composition comprising the dehydroepiandrosterone and ubiquinone. Therefore, the claimed invention in claims 1-15 and 17-48 is clearly seen to be anticipated by claim 159 of copending Application No. 10/072,010.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's remarks filed on July 9, 2003 in Paper No. 10 with respect to the rejection of 1-15 and 17-48 made under 35 U.S.C. 103(a) as being unpatentable over Prendergast (4,956,355), and the rejection of 1-15 and 17-48 made under the judicially

created doctrine of obviousness-type double patenting as being unpatentable over claims 13-19 of U.S. Patent No. 5,527,789, of record in the previous Office Action December 18, 2002 have been fully considered but are moot in view of the new ground(s) of rejection set forth above.

In view of the rejections to the pending claims set forth above, no claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
September 23, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER  
9/29/03